SECTION 2 – 510(K) SUMMARY

- **Name and Address of Applicant**

MAR 2 8 2008

Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, Ca 92610

Telephone: (949) 580-1555 Ext. 3325
Fax: (949) 580-1550
Attn: Jack Coggan, Director of Regulatory Affairs

Date: November 21, 2007

- **Name of the Device:** Prefense EDNS-9000 Series Central Nurse Station

- **The common or usual Name:** Monitor, physiological, patient (with arrhythmia detection or alarms) and Telemetry Monitoring Station.

- **The Classification:** The device has been classified as Class II by the Cardiovascular Device Classification Panel under 21 CFR Part 870.1025 "Monitor, Physiological, Patient (with arrhythmia detection or alarms)" per MHX and 21 CFR 870.2910 "Radiofrequency physiological Signal Transmitter and Receiver per DRG.

- **The legally marketed equivalence:** The predicate-marketed device is the CNS-9700 Series Central Nurse station and accessories per 510(k) K023475, commercial distribution dated October 16, 2002.

- **A description of the device:** The device is intended for use by medial professionals to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The Prefense EDNS-9000 Series Central Nurse Station will display and record physiological data from up to forty telemetry receiver/transmitters and generates an alarm when a measured parameter falls outside a pre-set limit or when life threatening arrhythmia is detected. Arrhythmia detection and alarm determination are functions of the telemetry receivers (Model ORG-9700 Multiple Patient Receiver, per 510K K071058 Commercial distribution certification dated June 29, 2007) transmitter (Model ZS-940PA, per 510(k) K043517 Commercial Distribution certification dated February 3, 2005).

- **A summary of the technological characteristics of the device compared to the predicate device:** The new device receives a small subset (non-invasive telemetry parameters) all of the same information as the predicate device, i.e., receives physiological signal from telemetry transmitters/receivers from ORG 9700 Multiple Patient Receiver signal simultaneously, receives and displays physiological information, generates audible and/or visual alarm indictors when an alarm violation is detected by the telemetry units, stores waveforms for review and printing as full disclosure, stores tabular and graphical trending data for review and printing, provides network communications using commercially available LAN/WAN products, provides remote data access through NetProse access software and records and prints physiological patient data.

  To date, no special controls or performance standards are known or established for this device.

The device is not sterile.

The device is not contacting patients. Therefore, no good laboratory practice studies were required per 21 CFR 58.

Design validation confirmed the operation of the software and hardware of the device is in accordance to the design specifications.

The device was subjected to electromagnetic, environmental, safety and performance testing procedures. These test verified the proper operation of the device. Design validation confirmed the operation of the software and hardware of the device is in accordance to the design specifications.

Therefore, based on the above, Nihon Kohden believes that the Prefense EDNS-9000 Series Central Nurse Station is substantially equivalent to the predicate device, CNS-9700 Series Central Nurse Station.

SECTION 3 – PROPOSED LABELING

A. Intended Use

The Prefense EDNS-9000 Series Central Nurse Station is intended for use by medical professionals to provide cardiac and vital signs monitoring for multiple patients within a medical facility.

The Prefense EDNS-9000 Series Central Nurse Station will display and record physiological data from up to forty telemetry receivers/transmitters and generates an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected. Arrhythmia detection and alarm determination are functions of the telemetry receivers/transmitters or individual beside monitor.

B. Device/Package Labels

The proposed product labels for the devices are presented in Attachment # 2

C. Proposed Packaging

Packaging for the device is depicted in Attachment # 2

D. Instruction for Use

The proposed instructions for use are provided with each packaged device and are presented in Attachment #11.

E. Advertisement/Promotional Literature

To date no advertisement or promotional literature for the Prefense EDNS-9000 Series Central Nurse Station has been created for distribution in the United States.

F. Contraindications, Precautions & Warnings

Warnings and cautions are listed in the Operator's Manual as shown in Attachment # 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2008

Nihon Kohden America, Inc.
c/o Mr. Jack Coggan
Regulatory Affairs Director
90 Icon Street
Foothill Ranch, CA 92610

Re: K073550
Trade/Device Name: Nihon Kohden Prefense EDNS-9000 Series Central Nurse Station
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment Measurement and Alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: February 29, 2008
Received: February 29, 2008

Dear Mr. Coggan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Angela C. Swinson for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): _____K073550_____

Device Name: Prefense EDNS-9000 Series Central Nurse Station

Indications for Use:

The Prefense EDNS-9000 Series Central Nurse Station is intended for cardiac and vital signs monitoring for multiple patients. The device will display and record physiological data from telemetry receivers/transmitters and alarms when a measured parameter falls outside a preset limit or when an arrhythmia is detected by the telemetry unit.

This product will be available for use by medical personnel on all patient populations with a medical facility.

Prescription use: ___x___ AND/OR Over - the – Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan C. Smith for B. Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073550

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